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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/102,865	06/23/1998	SHANTHA T. RAJU	P1096R1	2304

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EXAMINER
SCHWADRON, RONALD B

ART UNIT	PAPER NUMBER
1644	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/102,865	Applicant(s) Raju
	Examiner Ron Schwadron, Ph.D.	Art Unit 1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☐ Responsive to communication(s) filed on _____.

2a) ☒ This action is **FINAL.** 2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) 1-29 is/are pending in the application.

4a) Of the above, claim(s) 10-24 is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) 1-9 and 25-29 is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

1. Claims 1-9,25-29 are under consideration. Claim 1 has been amended.

RESPONSE TO APPLICANTS ARGUMENTS

2. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321© may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b)

3. Claims 1-9,25-29 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-7,10-16,20,35-39,41-44 of copending Application No. 09/183824. Although the conflicting claims are not identical, they are not patentably distinct from each other because while the two sets of claims differ in scope, both sets of claims encompass compositions/articles of manufacture that comprise the glycoprotein with the properties recited in claim 1 of the instant application. Therefore the two sets of claims would have been prima facie obvious to one of ordinary skill in the art.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Applicant has previously indicated that this rejection will be addressed by indication of allowable subject matter.

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 1-9,25-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kumpel et al. in view of Maras et al. (US Patent 5,834,251) and prior art disclosed in the specification (pages 1,2,19-21).

Kumpel et al. teach human monoclonal antibodies wherein the oligosaccharide profile differs depending on the culture conditions used to produce said antibodies. Kumpel et al. teach particular monoclonal antibodies wherein the vast majority of oligosaccharides found on said antibody is G2 (see abstract, Table 1, columns 1-3, and page 149, column 1, first incomplete paragraph). Said antibodies are in composition form wherein they are contained in a pharmaceutically acceptable carrier (eg. tissue culture media). The antibody 2B6 disclosed in Table 1 is an IgG1 antibody (see page 144, second column). Kumpel et al. teach that antibodies with predominantly G2 oligosaccharide have increased lysis of target cells in comparison to the same antibody which is produced in a manner that results in low levels of G2 (see Figure 3). Kumpel et al. do not teach a G2 containing antibody preparation of the degree of purity recited in the claims. Kumpel et al. do not teach the molecules of claims 6-9 or the claimed articles of manufacture. Maras et al. teach that B-1,4 Galactosyltransferase can be used to modify the oligosaccharide profile on a glycoprotein (see columns 12 and 16). Kumpel et al. teach that said enzyme is involved in the production of G2 oligosaccharides (see abstract). The prior art recited in the specification (pages 1,2,19-21) discloses that the antibodies, immunoadhesions and chimeric molecules recited in claims 6-9 were known in the art, as was the clinical use of said molecules. It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have created the claimed invention because Kumpel et al. teach particular monoclonal antibodies wherein the vast majority of oligosaccharides found on said antibody is G2 whilst Maras et al. teach that B-1,4 Galactosyltransferase can be used to modify the

oligosaccharide profile on a glycoprotein. One of ordinary skill in the art would have been motivated to do so because Kumpel et al. teach that antibodies with predominantly G2 oligosaccharide have increased lysis of target cells in comparison to the same antibody which is produced in a manner that results in low levels of G2 and the method taught by Maras et al, could have been used as an alternative method to produce G2 monoclonal antibodies or to produce a G2 antibody preparation with less G1 and GO oligosaccharides to further study the role of said oligosaccharides in antibody function. It would have been prima facie obvious to one of ordinary skill in the art to have created G2 oligosaccharide versions of the art known molecules recited in claims 6-9 because Kumpel et al. teach that antibodies with predominantly G2 oligosaccharide have increased lysis of target cells in comparison to the same antibody which is produced in a manner that results in low levels of G2 and Maras et al. teach that B-1,4 Galactosyltransferase can be used to modify the oligosaccharide profile on a glycoprotein (eg. to produce G2 oligosaccharide glycoproteins). One of ordinary skill in the art would have been motivated to do the aforementioned in order to produce G2 versions of the aforementioned glycoproteins for potential clinical evaluation. Said G2 glycoproteins would have been produced as the claimed articles of manufacture for use in clinical trials.

Regarding applicants comments, Kumpel et al. teach that antibodies with increased G2 oligosaccharide have increased lysis of target cells in comparison to the same antibody which is produced in a manner that results in low levels of G2 (see Figure 3). Kumpel et al. teach that "The "hypergalactosylated" anti-D (LD BRAD-3) promoted greater FcγRI- and FcγRIII- mediated lysis of erythrocytes in ADCC assays than the anti-D with a lower galactose content (HD BRAD-3)(as shown in Figures 3 and 4)." (see page 149, first column, first complete paragraph). One of ordinary skill in the art would have been motivated to produce the claimed invention because Kumpel et al. teach that antibodies with predominantly G2 oligosaccharide have increased lysis of target cells in comparison to the same antibody which is produced in a manner that results in low levels of G2 and the method taught by Maras et al, could have been used as an alternative method to produce G2 monoclonal antibodies or to produce a G2 antibody preparation with less G1 and GO oligosaccharides to further study the role of said oligosaccharides in antibody function.

6. No claim is allowed.

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office

action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

8. Papers related to this application may be submitted to Group 1600 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Papers should be faxed to Group 1600 at (703) 308-4242.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Ron Schwadron whose telephone number is (703) 308-4680. The examiner can normally be reached Monday through Thursday from 7:30 to 6:00. A message may be left on the examiners voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ms. Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703) 308-0196.

RONALD B. SCHWADRON
PRIMARY EXAMINER
GROUP 1800 1600

Ron Schwadron, Ph.D.
Primary Examiner
Art Unit 1644